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ABBOTT LABORATORIES

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

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|---------------------------------|---|---------------------------------------|
| SMITHKLINE BEECHAM CORPORATION, |) | Case No. C 07-5702 CW |
| d/b/a GLAXOSMITHKLINE, |) | |
| |) | <i>Related by Order to:</i> |
| Plaintiff, |) | |
| |) | <i>Case No. C 04-1511 CW</i> |
| vs. |) | |
| |) | ABBOTT LABORATORIES' ANSWER TO |
| ABBOTT LABORATORIES |) | COMPLAINT |
| |) | |
| Defendant. |) | The Honorable Judge Wilken |

Defendant Abbott Laboratories, by and through its undersigned counsel, hereby answers the Complaint of Smithkline Beecham Corporation, d/b/a GlaxoSmithKline ("Plaintiff") as follows:

INTRODUCTION

1. Paragraph 1 contains characterizations of Plaintiff's claims and states conclusions of law rather than allegations of fact to which a response is required. Insofar as a response is required, Abbott admits that protease inhibitors ("PIs") are promising HIV/AIDS therapies. Abbott also admits that it sells a PI called Norvir, which is used to treat HIV/AIDS, and that Norvir can be used to boost the efficacy of other PIs. Abbott further admits that effective December 3, 2003, it raised the Wholesale Acquisition Cost ("WAC") of Norvir from \$1.71 to \$8.57 per 100 mg capsule. Abbott denies the remaining allegations of paragraph 1.

2. Paragraph 2 contains characterizations of Plaintiff's claims and states conclusions of law rather than allegations of fact to which a response is required. Insofar as a response is required, Abbott admits that, on December 13, 2002, it entered into a non-exclusive license agreement with GSK, which generally permits GSK to promote the use of Norvir to boost the efficacy of Lexiva® (branded fosamprenavir), an HIV drug manufactured and/or marketed by GSK. Abbott also answers that the documents referenced in the Complaint speak for themselves and the quotes herein are taken out of context. Abbott denies the remaining allegations of paragraph 2.

3. Paragraph 3 contains characterizations of Plaintiff's claims and states conclusions of law rather than allegations of fact to which a response is required. Insofar as a response is required, Abbott denies the allegations in the first sentence of paragraph 3. Abbott also answers with respect to the second and third sentences of paragraph 3 that its 2006 Annual Report speaks for itself and the quotes herein are taken out of context. Abbott lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in the fourth sentence of paragraph 3 and therefore denies the same. Abbott denies the remaining allegations of paragraph 3.

4. Abbott admits that the Wall Street Journal article attached to the Complaint reports that one AIDS patient saw his insurance copayments jump from \$400 per month to \$1,000 per month when Abbott raised Norvir's price. Abbott also admits that separate class action lawsuits

1 claiming to be on behalf of consumers and third-party payors were filed in this Court. Abbott denies
2 the remaining allegations of paragraph 4.

3 **PARTIES**

4 5. Abbott lacks knowledge or information sufficient to form a belief about the truth of
5 the allegations contained of paragraph 5 and therefore denies the same.

6 6. Abbott admits that it is a corporation organized and existing under the laws of the
7 State of Illinois and that its headquarters and principal place of business is in Abbott Park, Illinois.
8 Abbott also admits that it sells pharmaceutical and nutritional products. Abbott further admits that it
9 markets its products in more than 130 countries, including California and the United States, and has
10 facilities in 14 states, including at least three in this District. Abbott denies the remaining allegations
11 of paragraph 6.

12 **JURISDICTION, VENUE AND INTRADISTRICT ASSIGNMENT**

13 7. Paragraph 7 states a conclusion of law rather than allegations of fact to which a
14 response is required. Insofar as a response is required, Abbott denies that it caused injuries within
15 this District through its acts and omission and further denies that GSK has suffered any damages as
16 alleged in its complaint.

17 8. Paragraph 8 states conclusions of law rather than allegations of fact to which a
18 response is required. Insofar as a response is required, Abbott admits that Plaintiff purports to bring
19 Count one under the Sherman Act, 15 U.S.C. § 1 *et seq.*; Count two under state common law; Count
20 three under the North Carolina Unfair Trade Practices Act, N.C. Gen. Stat. § 75-1.1; and Count four
21 under North Carolina's anti-monopolization statute, N.C. Gen. Stat. § 75-2.1. Abbott denies the
22 remaining allegations of paragraph 8.

23 9. Paragraph 9 states conclusions of law rather than allegations of fact to which a
24 response is required.

25 10. Paragraph 10 states conclusions of law rather than allegations of fact to which a
26 response is required. Insofar as a response is required, Abbott admits that it has business locations in
27 this District and transacts business in this District, but denies the remaining allegations of paragraph
28 10.

1 11. Paragraph 11 states a conclusion of law rather than allegations of fact to which a
2 response is required. Insofar as a response is required, Abbott denies the allegations of paragraph
3 11.

4 **FACTUAL BACKGROUND**

5 12. Abbott admits that HIV/AIDS is a disease that affects hundreds of thousands of
6 people on many continents. Abbott also admits that there are different treatments for HIV/AIDS
7 including HAART treatment. Abbott lacks knowledge or information sufficient to form a belief
8 about the truth of the remaining allegations contained in paragraph 12 and therefore denies the same.

9 13. Abbott admits that PIs work by blocking the action of HIV protease, an enzyme
10 needed for HIV to reproduce functional copies of itself. Abbott also admits that GSK, Abbott, BMS,
11 and others have designed, developed, and/or distributed PIs. Abbott further admits that some PI
12 regimens impose great pill burdens, require strict dietary requirements and have side effects. Abbott
13 also admits that different PIs present different degrees of impediment and efficacy, and that some
14 patients develop resistance to certain PIs. Abbott denies the remaining allegations of paragraph 13.

15 14. Abbott admits that it received a grant from the National Institutes of Health for early
16 discovery work related to certain compounds for the treatment of HIV. Abbott also admits that it
17 launched Norvir in 1996 and, at that time, upon information and belief, Norvir was used exclusively
18 as a PI. Abbott denies the remaining allegations of paragraph 14.

19 15. Abbott admits that Norvir is commonly used today to boost the effects of other PIs,
20 and that the boosting effect can reduce pill burden on patients, alleviate side effects, and reduce
21 incidence of resistance to some PI regimens. Abbott denies the remaining allegations of paragraph
22 15.

23 16. Abbott admits that physicians often prescribe Norvir to be co-administered with other
24 PIs, including those manufactured and/or marketed by Abbott's competitors. Abbott denies the
25 remaining allegations of paragraph 16.

26 17. Abbott admits that it licensed certain competitors the right to promote their PIs to be
27 administered with Norvir. Abbott denies the remaining allegations of paragraph 17.

28

1 18. Abbott denies the allegations in the first sentence of paragraph 18. Abbott lacks
2 knowledge or information sufficient to form a belief about the truth of the remaining allegations
3 contained in paragraph 18 and therefore denies same.

4 19. Abbott admits that in 2000, it received FDA approval to market a PI that was a
5 combination of lopinavir and ritonavir in one pill. Abbott denies the remaining allegations of
6 paragraph 19.

7 20. Abbott admits that, on December 13, 2002, it entered into a non-exclusive license
8 agreement with GSK, which generally permits GSK to promote the use of Norvir to boost the
9 efficacy of Lexiva® (branded fosamprenavir), an HIV drug manufactured by GSK. Abbott denies
10 the remaining allegations of paragraph 20.

11 21. Abbott admits that, on December 13, 2002, it entered into a non-exclusive license
12 agreement with GSK, which generally permits GSK to promote the use of Norvir to boost the
13 efficacy of Lexiva® (branded fosamprenavir), an HIV drug manufactured by GSK. Abbott denies
14 the remaining allegations of paragraph 21.

15 22. Abbott admits that it licensed certain competitors the right to promote their PIs to be
16 administered with Norvir. Abbott denies the remaining allegations of paragraph 22.

17 23. Abbott admits that it is the sole manufacturer of Norvir. Abbott denies the remaining
18 allegations of paragraph 23.

19 24. Abbott denies the allegations of paragraph 24.

20 25. Abbott answers that its documents speak for themselves and the quotes herein are
21 taken out of context. Abbott denies the remaining allegations of paragraph 25.

22 26. Abbott answers that its documents speak for themselves and the quotes herein are
23 taken out of context. Abbott denies the remaining allegations of paragraph 26.

24 27. Abbott answers that its documents speak for themselves and the quotes herein are
25 taken out of context. Abbott denies the remaining allegations of paragraph 27.

26 28. Abbott answers that its documents speak for themselves and the quotes herein are
27 taken out of context. Abbott denies the remaining allegations of paragraph 28.

28

29. Abbott admits that effective December 3, 2003, it raised the WAC of Norvir from \$1.71 to \$8.57 per 100 mg capsule. Abbott denies the remaining allegations of paragraph 29.

30. Abbott admits that it has raised the price of Norvir in the past and, in December 2003, it raised the WAC of Norvir from \$1.71 to \$8.57 per 100 mg capsule. Abbott also admits that it did not change the WAC of Kaletra in December 2003. Abbott lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 30 and therefore denies the same.

31. Abbott answers that the communications from the Organization of HIV Healthcare Providers speak for themselves. Abbott denies the remaining allegations of paragraph 31.

32. Abbott denies the allegations of paragraph 32.

33. Abbott denies the allegations of paragraph 33.

34. Abbott admits that the DHHS sent a warning letter to Abbott. The content of the letter speaks for itself. Abbott denies the remaining allegations of paragraph 34.

35. Abbott denies the allegations of paragraph 35.

36. Abbott denies the allegations of paragraph 36.

37. Abbott denies the allegations of paragraph 37.

RELEVANT MARKET

38. Abbott denies the allegations of paragraph 38.

39. Abbott denies the allegations of paragraph 39.

40. Abbott denies the allegations of paragraph 40.

41. Abbott denies the allegations of paragraph 41.

42. Abbott denies the allegations of paragraph 42.

HARM TO COMPETITION

43. Abbott admits that it voluntarily entered into a license agreement with GSK and other competitors. The terms of those license agreements speak for themselves. Abbott denies the remaining allegations of paragraph 43.

44. Abbott denies the allegations of paragraph 44.

45. Abbott admits that effective December 3, 2003 it raised the WAC of Norvir from \$1.71 to \$8.57 per 100 mg capsule. Abbott denies the remaining allegations of paragraph 45.

46. Abbott denies the allegations of paragraph 46.

47. Abbott denies the allegations of paragraph 47.

48. Abbott denies the allegations of paragraph 48.

DAMAGES

49. Abbott denies the allegations of paragraph 49.

50. Abbott denies the allegations of paragraph 50.

TRADE AND COMMERCE

51. Abbott denies the allegations of paragraph 51.

52. Abbott denies the allegations of paragraph 52.

CONTINUING WRONGDOING AND EQUITABLE TOLLING

53. Abbott denies the allegations of paragraph 53.

COUNT 1– VIOLATION OF SHERMAN ACT SECTION TWO (15 U.S.C. 4 2)

54. Abbott incorporates by reference its answers to the allegations contained in paragraphs 1 through 53 above as if fully set forth herein.

55. Abbott denies the allegations of paragraph 55.

56. Abbott denies the allegations of paragraph 56.

57. Abbott denies the allegations of paragraph 57.

58. Abbott denies the allegations of paragraph 58.

59. Abbott denies the allegations of paragraph 59.

60. Abbott denies the allegations of paragraph 60.

61. Abbott denies the allegations of paragraph 61.

62. Abbott denies the allegations of paragraph 62.

COUNT 2 – BREACH OF COVENANT OF GOOD FAITH AND FAIR DEALING

63. Abbott incorporates by reference its answers to the allegations contained in paragraphs 1 through 53 above as if fully set forth herein.

64. Abbott admits that, on December 13, 2002, it entered into a non-exclusive license agreement with GSK, which generally permits GSK to promote the use of Norvir to boost the efficacy of Lexiva® (branded fosamprenavir), an HIV drug manufactured by GSK. Abbott denies the remaining allegations of paragraph 64.

65. Abbott denies the allegations of paragraph 65.

66. Abbott denies the allegations of paragraph 66.

COUNT 3 — VIOLATION OF STATE UNFAIR TRADE PRACTICE STATUTE

67. Abbott incorporates by reference its answers to the allegations contained in paragraphs 1 through 53 above as if fully set forth herein.

68. Paragraph 68 states a conclusion of law rather than allegations of fact to which a response is required. Insofar as a response is required, Abbott admits that Plaintiff purports to bring this claim under the North Carolina Unfair Trade Practices Act, N.C. Gen. Stat. § 75-1.1, and that Plaintiff seeks treble damages. Abbott denies the remaining allegations of paragraph 68.

69. Abbott denies the allegations of paragraph 69.

70. Abbott denies the allegations of paragraph 70.

71. Abbott denies the allegations of paragraph 71.

72. Abbott denies the allegations of paragraph 72.

COUNT 4 – VIOLATION OF STATE PROHIBITION AGAINST MONOPOLIZATION

73. Abbott incorporates by reference its answers to the allegations contained in paragraphs 1 through 53 above as if fully set forth herein.

74. Paragraph 74 states a conclusion of law rather than allegations of fact to which a response is required. Insofar as a response is required, Abbott denies the allegations of paragraph 74.

75. Abbott denies the allegations of paragraph 75.

76. Abbott denies the allegations of paragraph 76.

GROUND OF DEFENSE

Without assuming any burden it would not otherwise bear, Abbott asserts the following defenses and reserves its right to raise additional defenses if and when deemed appropriate as the case progresses:

FIRST DEFENSE

Plaintiff's complaint and each purported cause of action set forth therein against Abbott fails to state a claim upon which relief can be granted.

SECOND DEFENSE

Plaintiff's complaint and each purported cause of action is barred because each of the alleged acts and/or omissions was justified, fair, lawful, and/or not fraudulent.

THIRD DEFENSE

Plaintiff's complaint and each purported cause of action is barred because Abbott has patents that cover the products sold in the alleged relevant markets and the method of combining PIs with Norvir.

FOURTH DEFENSE

Plaintiff's complaint and each purported cause of action is barred because Abbott has not engaged in below-cost pricing under any measure.

FIFTH DEFENSE

Plaintiff's complaint and each purported cause of action is barred because Abbott did not have the requisite monopoly power.

SIXTH DEFENSE

Plaintiff's complaint and each purported cause of action is barred because Plaintiffs did not suffer an antitrust injury.

SEVENTH DEFENSE

Plaintiff's complaint and each purported cause of action is barred because Abbott's actions did not have an anticompetitive effect.

EIGHTH DEFENSE

Plaintiff's complaint and each purported cause of action is barred by the applicable statute of limitations.

NINTH DEFENSE

Plaintiff's complaint and each purported cause of action is barred by the doctrine of laches.

TENTH DEFENSE

Plaintiff's complaint and each purported cause of action is barred by the doctrine of unclean hands.

ELEVENTH DEFENSE

Plaintiff's complaint and each purported cause of action is barred by the doctrine of accord and satisfaction.

TWELFTH DEFENSE

Plaintiff's complaint and each purported cause of action is barred because GSK assumed the risk that Abbott would raise the price of Norvir.

THIRTEENTH DEFENSE

Plaintiff's complaint and each purported cause of action is barred by the doctrine of estoppel.

FOURTEENTH DEFENSE

Plaintiff's cause of action for breach of the covenant of good faith and fair dealing is barred by the defense of illegality.

FIFTEENTH DEFENSE

Plaintiff's complaint and each purported cause of action is barred by the doctrine of waiver.

PRAYER FOR RELIEF

WHEREFORE, Defendant Abbott Laboratories denies Plaintiff's "Petition For Relief," denies that Plaintiff is entitled to an injunction or judgment in any amount, and prays that Plaintiff's claims be dismissed in their entirety with prejudice and that Abbott be awarded its reasonable costs, attorneys' fees and such other and further relief as may be appropriate.

Winston & Strawn LLP
101 California Street
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1 Dated: April 25, 2008

WINSTON & STRAWN LLP

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3 By: /s/ Charles B. Klein

4 Attorneys for Defendant
5 ABBOTT LABORATORIES
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